Remarks

I. Status of the claims

Claims 1, 4, 7-12, 23 and 28-33 are pending and stand rejected. Claim 30 has been amended. No new matter has been added.

II. Amendments to the claims

Claim 30 has been amended to add the language "wherein said pharmaceutically active agent, hydroxyethyl cellulose and hydroxypropyl methylcellulose, ethylcellulose, talc, magnesium stearate, and granulating and tableting aids, are provided as a matrix." This language is analogous to language found in the other independent claims. Additionally, support for this amendment can be found, for example, in the specification at page 5, first paragraph.

III. Claim Rejections Under 35 U.S.C. § 112, second paragraph

Claims 1, 4, 7-12, 23, and 28-33 stand rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite. Specifically, the Examiner contends that the "[i]t is not clear whether the percentages of the itemized agents in the claims are part of the matrix." Applicants respectfully traverse.

Applicants submit that the plain language of the claim is clear in providing that the recited percentages of agents are a part of the matrix. The claim states "wherein said acrylic acid cross-linked polymers, hydroxyethyl cellulose hydroxypropyl methylcellulose, talc and magnesium stearate are provided as a matrix." *Claim 1,* (emphasis added). The word "said" indicates that the list of agents that follows has antecedent basis in the preceding list of agents, which recites the percentages. Withdrawal of this rejection is respectfully requested.

IV. Claim Rejections under 35 U.S.C. § 102(b)

The Examiner has rejected claims 1, 4, and 8-10 as being allegedly anticipated by U.S. Patent No. 4,252,786 to Weiss et al. ("Weiss"). According to the Examiner, Weiss teaches a

controlled release tablet comprising polymers of acrylic acid crosslinked with polyalkenyl alcohols. In particular, the Examiner contends that Weiss discloses that the "the composition comprises hydroxymethyl cellulose, ethyl cellulose and hydroxypropyl methyl cellulose talc." *Office Action* at p. 3. Applicants respectfully traverse.

To anticipate a claim under §102(b), a reference must teach each and every element of the claim, either expressly or inherently. M.P.E.P. § 2131. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union oil Co. of* California, 8144. F. 2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1566 (Fed. Cir. 1990).

Weiss fails to disclose 1-15% by weight of a mixture of hydroxyethyl cellulose and hydroxypropyl methylcellulose. Weiss merely describes hydroxypropyl methylcellulose in a coating for a compressed tablet, but not hydroxyethyl cellulose.

Additionally, Weiss does not describe that the recited ingredients are provided in a matrix, as claimed. The hydroxypropyl methylcellulose described in Weiss is provided as a coating solution, which is applied to the tablet, and is not a part of the matrix. Carbopol 934, meanwhile, is a part of the Weiss tablet. Thus, these two ingredients cannot be considered to be "provided as a matrix," as recited in the instant claims. For at least these reasons, Applicants request withdrawal of this rejection.

V. Claim rejections under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1, 4, 7-12, 23 and 28-33 as being allegedly obvious over Weiss in view of U.S. Patent No. 4,309,405 to Guley et al. ("Guley") taken with U.S. Patent No. 4,218,433 to Kooichi et al. ("Kooichi"). The Examiner relies on Weiss for reasons discussed with respect to the 102(b) rejection. *Office Action* at p. 5. The Examiner further states with regard to claims 11 and 29 that one skilled in the art would have been motivated to switch aspirin, taught by Weiss, to naproxen since both are non-steroidal antiinflammatory drugs. *Office Action* at p. 5. The Examiner relies on Guley for describing talc and calcium stearate, stating that one skilled in the art would have been motivated to substitute calcium for magnesium stearate, "and expect a successful result in doing so because both calcium and magnesium are alkaline earth metals." Finally, the Examiner relies on Kooichi for describing a controlled release tablet comprising "methacrylic and methacrylic esters." *Id.* Applicants respectfully traverse.

In order to establish a *prima facie* case of obviousness, the Examiner must determine the scope and content of the prior art, ascertain the differences between the claimed invention and the prior art and resolve the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 (1966). Once the Graham factual inquiries have been resolved, the Examiner must explain why the differences between the cited references and the claims would have been obvious to one of ordinary skill in the art. Fed. Reg. Vol. 72, No. 195, p. 57527. The Supreme Court in *KSR* stressed that "obviousness cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR* 127 S.Ct. 1727, 1740 (2007); see also Fed. Reg. Vol. 72, No. 195, p. 57529.

"The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious." Fed. Reg. Vol. 72, No. 195 at p. 57528.

Weiss, either alone or in combination with Guley and Kooichi, fails to render the present claims obvious. As discussed above, Weiss provides a tablet, and a coating for the tablet. In particular, Weiss fails to include 1 to 15% by weight of hydroxyethyl cellulose and hydroxypropyl methylcellulose, as claimed. Furthermore, Weiss describes hydroxypropyl methylcellulose as a part of a coating for the tablet, while Carbopol is included as a part of the matrix tablet itself. Based on these teachings, one skilled in the art would have no rational basis for modifying Weiss in order to arrive at the present claims.

Guley and Kooichi fail to remedy the deficiencies of Weiss. Guley describes sustained release pharmaceutical compositions containing at least one drug in both an inner compressed core and an outer sugar layer. *Guley* at col. 1, ll. 11-15. Kooichi describes a constant rate eluting medicinal tablet. *Kooichi* at col. 1, ll. 6-7. Kooichi and Guley, when combined with the teachings of Weiss, fail to provide any rational basis for arriving at the instant claims. Specifically, neither Kooichi or Guley provides any teaching to use of 1-15% of a mixture of hydroxyethyl cellulose and hydroxypropyl methylcellulose. For at least these reasons, Applicants request withdrawal of this rejection.

VI. Provisional Non-Statutory Double Patenting

Claims 1, 4, 7-12, 23 and 28-33 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent Application No. 11/473,386 ("the '386 application"). Claims 1, 4, 7-12, 23 and 28-33 remain rejected under the judicially created doctrine of obviousness-type double patenting as being

unpatentable over claims 1-28 of U.S. Patent No. 7,090,867. Applicants respectfully request that the Examiner hold in abeyance this obviousness-type double patenting rejection until allowable subject matter is indicated, at which point Applicants will file a terminal disclaimer if necessary.

VII. Conclusion

In view of the above amendments and remarks, the Applicants believe that the pending claims are in condition for allowance. If a telephone conversation with Applicants' attorney would expedite prosecution of the application, the Examiner is urged to contact the undersigned.

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Respectfully submitted,

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